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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/884,728 | 06/19/2001 | Clifford J. Dwyer | CRD-0940 | 3625 |

27777 7590 03/11/2003

AUDLEY A. CIAMPORCERO JR.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

MILLER, CHERYL L

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/884,728 | Applicant(s) DWYER ET AL. | |
| | Examiner Cheryl Miller | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 23 December 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Response to Arguments***

Applicant's arguments filed December 23, 2002 have been fully considered but they are not persuasive. Referring to applicant's argument to the Wilson reference, flat is defined as a level piece of land, without obstacles. Wilson's wire reinforcement layer is indeed level without obstacles. Examiner notes that only the *layer* is claimed to be flat, not the cross-sectional shape. The cross-sectional shape is not claimed until dependent claim 3. Therefore, the Wilson rejection stands. Referring to applicant's argument to the Truckai reference, Truckai is used as a teaching reference for rectangular cross section. The Truckai wire reinforcement is rectangular in order to increase the flatness, in fact Truckai even refers to the wires as "flat strands" (col.2, lines 16-18, 33-35), and clearly the flat strands reduce the profile of the sheath. Referring to applicant's argument to the Kocak reference, Kocak teaches a silicone or PTFE coating on the inner layer of the sheath to provide smoothness and to minimize friction (therefore, increase lubricity. Also, because the materials used to cost the Kocak's sheath are the same materials used by the applicant, inherently, they will have the same properties i.e., lubricity. In addition, it is well know in the art that silicones are lubricous materials.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-2 and 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilson et al. (USPN 6,425,898 B1, as cited in previous office action). Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10) having a guidewire lumen (28), a stent bed (24), a sheath (40) having an enlarged section (col.4, lines 35-38; fig.5) coaxial with the stent bed, the sheath formed from an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70), which extends between the inner and outer layers (fig.8). Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.7, lines 65-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1, cited in previous office action) in view of Truckai (USPN 5,176,660, cited in previous office action). Wilson discloses a delivery apparatus with a wire reinforced sheath substantially as claimed (see above). Wilson does not disclose however, wires having a rectangular cross section and dimensions for such wires. Referring to claims 3-4, Truckai teaches a layered delivery sheath (catheter, 10) having flat wire reinforcement (16) with rectangular cross-sections (fig.5) and dimensions similar to the dimensions claimed (col.2, lines 60-61; col.4, lines 1-5, 39), in order to increase the stiffness of the sheath while minimizing

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profile (col.2, lines 15-21, 42-43; col.4, lines 1-7; col.5, lines 11-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Wilson's wire reinforced sheath with Truckai's geometric teaching flat *rectangular* wires used in sheaths, in order to provide a smooth and stiff delivery sheath having a minimized profile.

Referring to claim 5, Wilson discloses wire reinforcement arranged in a braided configuration (col.7, lines 65-67).

Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (USPN 6,425,898 B1, cited in previous office action) in view of Kocak (USPN 4,705,511, cited in previous office action). Referring to claims 8 and 15, Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10) having a guidewire lumen (28) and a stent bed (24), a sheath (40) having an enlarged section (col.4, lines 35-38; fig.5) coaxial with the stent bed, the sheath formed from an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70). Wilson does not however, disclose a lubricious coating on an inner polymeric layer. Kocak teaches in the same field of endeavor, a delivery sheath (38, 138) for introducing catheters and medical devices to the vascular system (col.4, lines 15-16), the sheath having a wire reinforcing layer (40, 140), polymeric layers (42, 142) and additional lubricious coating (41, 141), wherein the purpose of the coating is to provide a smooth, low friction surface (col.5, lines 56-61). Kocak discloses coating materials comprising PTFE or silicone (col.5, lines 65-67; col.3, lines 8-17; col.4, line 59; col.4, lines 63-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's teaching of lubricious coating such as silicone on a delivery sheath, with

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Wilson's delivery sheath in order to provide a sheath with a smooth, lubricious, low friction surface.

Referring to claim 9, Wilson discloses a reinforcement layer sandwiched between an inner and outer polymeric layer and extending the length of the sheath (fig.8).

Referring to claims 10-11, Wilson discloses a sheath having a wire reinforcement layer, however does not disclose a rectangular cross section for the wire and dimensions for such a wire. Kocak teaches in the same field of endeavor, a wire reinforcement layer having a rectangular cross section with specific dimensions and made of stainless steel in order to provide a low, smooth, profile and increased flexibility (fig.5; 140; col.7, lines 16-32). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Kocak's geometric teaching of using a dimensioned rectangular cross section stainless steel wire reinforcement layer in a sheath, with Wilson's sheath reinforcement layer, in order to provide a low smooth profile with flexibility.

Referring to claim 12, Wilson discloses wire reinforcement arranged in a braided configuration (col.7, lines 65-67).

Referring to claims 13 and 14, Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.7, lines 65-66).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

March 6, 2003



**CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**